DCH/LPH-501 (12/04)

Michigan Department of Community Health **Board of Pharmacy**

P.O. Box 30670 Lansing, Michigan 48909 (517) 335-0918

www.michigan.gov/healthlicense

PHARMACY LICENSURE INSTRUCTIONS

Authority: P.A. 368 of 1978, as amended This form is for information only

NOTE: It is your responsibility to have all required documentation sent to the Board of Pharmacy. Questions regarding your application can be directed to the Michigan Board of Pharmacy at (517) 335-0918 three weeks after the date you sent the application. Please allow 4-6 weeks processing time. An application accompanied by the appropriate fee is valid for two years. If an applicant fails to complete the requirements for licensure within two years from the date of filing the application, the application is no longer valid.

OPENING A NEW PHARMACY

- 1. The application, ADP System Approval Request form, and Self-Inspection form should be completed in their entirety and returned to the board office with appropriate fees.
- 2. Applicants that are partnerships, corporations, or operating under an assumed name must file their application for a pharmacy license along with copies of:
 - 1) Partnership Certificates
 - 2) Articles of Incorporation and/or Assumed Name Certificates.
- 3. Complete the information on the application as to the opening date of the pharmacy, name and telephone number of person to contact.
- 4. Complete the Controlled Substance application and submit it to the board office along with the \$85.00 fee. A separate controlled substance license is required for each business location from which you manufacture, distribute, or dispense controlled substances.

Upon receipt of fees and all pertinent documents, your application will be reviewed for compliance with Administrative Rules 11 and 12 of the Michigan Board of Pharmacy. If the application and checklist are satisfactory, a permanent identification number will be assigned, and a pharmacy and controlled substance license will be issued.

NOTE TO OUT-OF-STATE APPLICANTS - Section 333.17748 of the Michigan Public Health Code and Rule 338.477 of the Administrative Rules of the Michigan Board of Pharmacy require pharmacy applicants to designate a licensed pharmacist to be in charge. A pharmacist-in-charge must hold a license in the state where the pharmacy is located. You will not receive a Michigan pharmacy license without complying with this requirement.

SALE OR TRANSFER OF A PHARMACY

The following changes constitute a transfer:

- 1. Complete (100%) change of ownership in existing pharmacy.
- 2. Sale of stock from original owner to new owner.
- 3. Widow/widower of owner who is not listed as an owner in existing pharmacy.

If one of the above applies to your situation, you must submit the following:

1. The application, ADP System Approval Request form, and Self-Inspection form should be completed in their entirety and returned to the board office with appropriate fees. You are <u>not</u> required to file a new controlled substance application and fee.

- 2. Affidavits from both buyer and seller stating the actual consummation date of the sale or transfer. Please submit name and telephone number of person to contact.
- 3. If the application indicates that the pharmacy ownership will be a partnership, corporation, or operating under an assumed name, the applicant must submit copies of:
 - 1) Partnership Certificates
 - 2) Articles of Incorporation and/or Assumed Name Certificates

Upon receipt of fees and all pertinent documents, including the Affidavit that states when the sale or transfer will occur, your application will be reviewed for compliance with Administrative Rules 11 and 12 of the Michigan Board of Pharmacy. If the application and checklist are satisfactory, a permanent identification number will be assigned, and pharmacy and controlled substance license will be issued.

NOTE TO OUT-OF-STATE APPLICANTS - Section 333.17748 of the Michigan Public Health Code and Rule 338.477 of the Administrative Rules of the Michigan Board of Pharmacy require pharmacy applicants to designate a licensed pharmacist to be in charge. A pharmacist-in-charge must hold a pharmacist license in the state where the pharmacy is located. You will not receive a Michigan pharmacy license without complying with this requirement.

RELICENSURE OF A PHARMACY (PREVIOUSLY LICENSED IN MICHIGAN)

The applications for the Pharmacy Relicensure and Controlled Substance license should be completed in their entirety and returned to the board office with the appropriate fees.

RELOCATION OF A PHARMACY

- 1. The application, ADP System Approval Request form, and Self-Inspection form should be completed in their entirety and returned to the board office with the \$55.00 fee. You are <u>not</u> required to file a new controlled substance application and fee.
- 2. Complete the information on the application about the proposed date of change of location, person to contact and telephone number.

Upon receipt of the fee and all pertinent documents, your application will be reviewed. If the application and checklist are satisfactory, the same permanent identification number will be retained, and a new pharmacy and controlled substance license will be issued to reflect the new address.

If a pharmacy area is moving within the building, no fee is required. No notification to the board office is necessary.

MISCELLANEOUS PHARMACY CHANGES

The following changes constitute miscellaneous changes, which may require a fee:

- 1. Partner or stockholder change.
- 2. Change in name of store/corporation where no change in ownership occurs.
- 3. Change in pharmacist-in-charge designation.

If one of the above applies to your situation, you must contact the board office at (517) 335-0918 to request an Application for Miscellaneous Pharmacy Change.

CLOSING OF A PHARMACY

The owner of a pharmacy being closed must notify the Michigan Board of Pharmacy of the effective closing date of the pharmacy and must return the current pharmacy license and controlled substance license to the Board office. The Board of Pharmacy must be notified about the disposition of the prescription files and prescription drugs for both controlled substances and non-controlled substances.

Upon receipt of the above information, our files for your pharmacy will indicate that it is closed.

For information concerning Federal Drug Enforcement Administration (DEA) requirements for pharmacy closings, contact the DEA at their Detroit office, 1-800-882-9539.								
DEA INFORMATION								
You may also apply to the Drug Enforcement Administration (DEA) for registration under the Federal Controlled Substances Act at the same time you apply for the Board of Pharmacy application. A federal application may be obtained from the Department of Justice Drug Enforcement Administration, 431 Howard Street, Detroit, Michigan 48226. The telephone number is 1-800-882-9539. All questions concerning the federal license should be directed to that office.								
3								

Michigan Department of Community Health

Board of Pharmacy

APPLICATION FOR PHARMACY LICENSE

SECTION I - Pharmacy Information - Complete this section in its entirety. Type or Print Only

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Board of Pharn	•					
P.O. Box 3067						
Lansing, MI 48						
(517) 335-091 www.michigan.gov/health	18 nlicense					
APPLICATION FOR PHARI Authority: Public Act 368 of 1978, If this form is not completed, a license						
A controlled substance license is required for every distributes, or dispenses any controlled substance in Michiga 368 of 1978, as amended. Information on obtaining a Fedobtained by contacting the Regional Branch, Drug Enforces	gan as described in Article 7 of deral controlled substance licen	f Public Act se may be	Boar	d Use	⊋ Only	
Detroit, MI 48226 (Telephone 1-800-882-9539).	·	·	License Number			
ECTION I - Pharmacy Information - Complete	e this section in its entir	ety.	Date of Licensure			
Type or Print Only						
I AM APPLYING FOR THE FOLLOWING:						
□ New Store License/Controlled Substance - Fee	: \$180.00 71-5301-375701	Propose	d Opening Date of Pha	rmac	à:	
□ Store Transfer - Fee: \$180.00 71-5301-375701		Proposed Date of Store Transfer:				
□ Pharmacy Relicensure - Fee: \$200.00 71-530	1-375706					
☐ Relocation - Fee: \$55.00 71-5301-33		Proposed Date of Relocation:				
Controlled Substance License: Complete the a	attached DCH/LPH-090 form	and retur	n with 1 year fee of \$85	5.00.		
Your check or money order drawn on a US financial institut SEND CASH. Fees are deposited upon receipt and can only	tion and made payable to the S y be refunded under refund rule	TATE OF I	MICHIGAN must accomp ted by the Department.	any th	nis application. DO NOT	
I AM APPLYING AS (check one from eac	ch category):					
Type of Pharmacy			Type of Owr	<u>nersl</u>	<u>hip</u>	
□ Retail □ HMO			Partnership		Individual Owner	
☐ Hospital ☐ Educational Instituti	ion Pharmacy		Private Corporation		Public Corporation	
Name of Pharmacy	*If Transfer,	Give Name	of Former Pharmacy and	MI pe	ermanent I.D. Number	
Name of Contact Person	Phone Numb	er of Conta	act Person			
Street Address	City		State		ZIP Code	
f Relocation, Give New Street Address	City		State		ZIP Code	
Business Telephone Number	County		Federal	Emplo	oyer (Tax) I.D. Number	

DCH/LPH-060 (12/04)

Dago 1 of 2

SECTION II

Name of Corporation (If Applicable)

List the names, MI Permanent I.D. Numbers, and percentage of stock owned by each individual who is a Pharmacist licensed in Michigan. If none, indicate "none" below.

If Relicensure or Relocation, List Pharmacy MI Permanent I.D. Number

Pharmacist's Name	MI Permanent I.D./License Number	Percentage of Stock Owned

The Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

DCH/LPH-060 (12/04)							Page 2 of 2
Name							
SECTION III - Designation of Pharmacist-In-	-Charge						
The individual named below is designated as the state laws and Board of Pharmacy rules regulating				for com	oliance	with f	ederal and
For Michigan Pharmacy: Michigan Pharma	icist-In-Charge		MI Perm	nanent I.I	D. Num	ber	
For out-of-state Pharmacy: Out-of-State Pharmacy	rmacist-In-Char	rge	Pharmac	ist Licen:	se Num	ber	
SECTION IV - Attach a detailed explanation			ked below.				
Has any individual director, employee, officer, misdemeanor or a felony?	owner, or stock	cholder ever been o	convicted of a		Yes		No
 Has any individual director, employee, officer, pharmacy, manufacturer, or wholesale distribu a. been denied a license or federal registration b. had its license or federal registration limited c. been subject to any other criminal, civil, or a 	tor which has n? I, surrendered,	suspended, or revo			Yes		No
 Has any pharmacist owner, Michigan pharmace ever had a license or federal registration denied, limited, reprimanded, suspended, ob. been subject to any other criminal or civil p 	or revoked?	rector, employee, c	fficer, or stockholder		Yes		No
SECTION V - Relocation Information							
New Street Address							
City		State		Zip	Code		
New Business Telephone Number with Area Code		County					
SECTION VI							
List the names and addresses of all partners, offic pharmacy is a privately held corporation, attach a							cy. If the
NAME AND ADDRESS	т	ITLE	AMOUNT OF STOCK OWNED (%)	SOCIA	L SEC	JRITY	NUMBER
I understand that it is the policy of this agency authorize this agency to use the information prov Records Division of the Michigan Department of	to secure a cri vided in this ap State Police or	plication to obtain a other law enforcen	a criminal conviction hist nent or judicial record-ke	ory file s eping or	earch fr ganizat	om th	e Central
I further consent to the release of information t registration, or specialty certification board of tanother country.							
The statements in this application are true and capplication. In signing this application, I am application or revocation of my license and that s	aware that a f	false statement or	dishonest answer may				

Date

Signature of Applicant

Michigan Department of Community Health Board of Pharmacy

P.O. Box 30670 Lansing, MI 48909 (517) 335-0918

www.michigan.gov/healthlicense

PHARMACY ADP SYSTEM APPROVAL REQUEST

Authority: Public Act 368 of 1978, as amended If this form is not completed, a license will not be issued.

PRESCRIPTION RECORDS: Checklist for Automated Data Processing (ADP) System. If a computer (ADP) system is used, please answer the following questions:

Type or Print Only										
Name of Pharmacy						N	lichigan Permanent I	.D. Numb	oer and Expi	ration Date
Street Address of Pharmacy							Pharmacy Telepho	one Num	ber	
City							State	ZIP Co	ndo.	
Sity Site of the s						State	ZIFC	ode		
Name of ADP Software System							The Terminal Syst	em is (C	heck One)	
							☐ On Lir	ne	☐ Stan	d Alone
Company Name				Com	pany Telephone Number	Company Represe	entative N	Vame		
Street Address of Company										
City							State	ZIP Co	ode	
1. The information entered on the	ADP	recor	d mu	st ind	clude	e, but is not limited to, the fo	llowing (check app	ropriate	box):	
CR = Computer Record	L	= Rx	Label	I						
Prescription Number		CR		L		Manufacturer or Supplie	er of Drug Disper	ised	☐ CR	
Patient's Name		CR		L		Name, strength, dosage prescribed and dispens		-		
Patient's Address		CR		L		Is drug dispensed DAW	?		☐ CR	
Prescriber's Name		CR		L		Date and initials of disponiginal and each refill	ensing pharmaci	st on	☐ CR	
Prescriber's DEA Number		CR		L		Date of Rx issuance			□ CR	
Number of Authorized refills		CR		L						
Are computer prescription r of Board agents?	ecor	ds ret	aine	d at	the	pharmacy for five years	subject to inspec	tion	☐ Yes	□ No
3. Is a R.Ph security code req	uired	l to a	tivat	te th	e Al	DP System in the A.M.?			☐ Yes	□ No
Do any other pharmacy or	store	pers	onne	l ha	ve a	ccess to the individual R	.Ph. codes?		☐ Yes	□ No
If yes, who?										
4. Are ALL prescriptions enter	ed in	ito the	e AD	P sy	/ste	m including those that are	e not refillable?		☐ Yes	□ No
5. Does the ADP system prov prescription data that is 16 16 months?								an	☐ Yes	□ No

	PH-800 (01/05)		ſ	Page 2 of 2
NAME				
6.	Is the ADP system capable of producing a hard copy printout of all original and refilled prescription data?		Yes	□ No
	Does this include			
	Prescription-by-prescription audit trail (specific patient)? Refill-by-refill audit trail (specific prescription)?		Yes Yes	□ No
	Could a controlled substance audit be done on:			
	A drug by each strength (15 mg, 10 mg, 5 mg) A drug by dosage form (tablets, capsules)?		Yes Yes	□ No □ No
	Drugs written by specific prescriber?		Yes	□ No
	Are hard copy printouts available for immediate review for all computer entries since the last controlled substance inventory?		Yes	□ No
7.	Does the pharmacy maintain a computer generated daily log for new and refill controlled substance prescriptions that includes a statement signed by the pharmacist at the end of each working day that the ADP information on Rx's he/she filled:			
	\square Has been reviewed? \square Is correct? \square Is complete? \square Has R.Ph signature	e?		
	☐ Contains the pharmacist's identifying designation?			
	Is this log maintained at the pharmacy for five years?		Yes	□ No
8.	Describe the system of recording new prescriptions and refill information in the event of down-time on the ADP system.	_		
9.	Describe the arrangements made with the ADP system supplier for continuity of records in the event of contract termination.			
10.	Are prescription records subject to confidentiality?		Yes	□ No
	Explain: ————————————————————————————————————			
11.	Is there a safeguard built into the system in case of power failure?		Yes	□ No
	Explain:			
	CERTIFICATION			
l, -	Print or Type Name, R.Ph., certify that my responses to this checklist are true an	d accu	rate	
an	d that I am employed as the Pharmacist-in-Charge or the Owner of this pharmacy.			

The Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

Date

Signature of Pharmacist-in-Charge/Owner

Michigan Department of Community Health **Board of Pharmacy**

P.O. Box 30670 Lansing, MI 48909 (517) 335-0918 www.michigan.govhealthlicense

PHARMACY SELF-INSPECTION FORM

Authority: Public Act 368 of 1978, as amended If this form is not completed, a license will not be issued

Time or Drint Only

		Date Opening, Transferring and Relocating
Street Address	City	
State	ZIP Code	County
Pharmacy Telephone Number	Pharmacy Hou	rs
Non-Pharmacist Owner of Pharmacy	Name of Pharn	nacist-in-Charge and MI License #
Non-Pharmacist Owner of Pharmacy	Employee Phar	rmacist and MI License #
Non-Pharmacist Owner of Pharmacy	Employee Phar	rmacist and MI License #
1		
Owner of Pharmacy	Employee Pha	rmacist and MI License #
Owner of Pharmacy Is the pharmacy approved for Intern		rmacist and MI License # - If Yes, Please complete the following:
Is the pharmacy approved for Intern	Training?	
Is the pharmacy approved for Intern	Training?	- If Yes, Please complete the following:
Is the pharmacy approved for Intern	Training?	- If Yes, Please complete the following: f Intern and MI License #
Is the pharmacy approved for Intern Name of Intern and MI License # Name of Intern and MI License #	Training?	- If Yes, Please complete the following: f Intern and MI License # of Intern and MI License #

Each pharmacy must be equipped with proper pharmaceutical utensils so that prescriptions can be properly filled and compounded and U.S. Pharmacopoeia and National Formulary preparations properly prepared.

PHARMACY CHECKLIST

		tions: Please indicat	- -	appropriate box as indicated.					
1	Does the pharmacy have the necessary technical equipment to compound and dispense prescription drugs?							No	
	i	a. Are three separat	te prescription files maintair	ned?		Yes		No	
	Schedule 2 Schedules 3,4, and 5 Other Legend Drugs								
	b. Prescription medication containers available in appropriate sizes?							No	
	(c. Safety closure pre	escription containers availal	ble in appropriate sizes and used routinely?		Yes		No	
	(d. Schedule 5 OTC	sales record book is mainta	nined?		Yes		No	

DCH/LPH-810 (12/04)	Page 2 of 3
NAME	

2.	Is there a well lighted, ventilated area of 150 square feet minimum devoted entirely to the pharmacy area?		Yes		No
3.	Clean and sanitary conditions?		Yes		No
4.	Prescription counter has at least 10 square feet work area plus 4 square feet for each additional pharmacist on duty, free of obstruction?		Yes		No
5.	Does the pharmacy occupy less than the entire area controlled by the licensee? If no, does the licensee control the entire area in which the pharmacy is located? If yes, does the pharmacy have a permanent partition enclosure from floor to ceiling that is lockable?	0 0 0	Yes Yes	0 0	No No
6			Yes		No No
	Sink with hot and cold running water?	_	Yes	_	No
1.	Refrigerator of adequate capacity?		Yes		No
8.	List the names of two (2) pharmacy reference texts or electronic media on site that pertain to drug interactions, drug product composition, and pharmacology.				
9.	Current copy of the Michigan Public Health Code - Dated:		Yes		No
10.	Current Michigan Pharmacy Administrative Rules - Dated:		Yes		No
11.	Are all licenses of pharmacists conspicuously displayed?		Yes		No
12.	Will all prescription labels indicate brand name, generic name, and name of manufacturer or distributor if drug product selection is utilized?		Yes		No
13.	Do pharmacists number, initial, and date all original prescriptions?		Yes		No
14.	Will the manufacturer's or distributor's name be indicated on all prescriptions where drug product selection is utilized or if prescription is written generically?		Yes		No
15.	Are all prescriptions retained for five years?		Yes		No
16.	Have all outdated drugs been removed from the prescription department shelves?		Yes		No
17.	Has DEA Registration been applied for?		Yes		No
18.	Have DEA Registration and Order Forms been received?		Yes		No
	DEA Registration Number				
	Expiration date of DEA Registration				
19.	Have you applied for central record keeping with DEA and the Board of Pharmacy? If applying, at what address will the records be kept?		Yes		No
	Street Address				
	City State Zip Code				
20.	Are controlled substances stored in a cabinet?		Yes		No
	Is this cabinet secured to the floor or wall?		Yes		No
	Is this cabinet substantially constructed and securely lockable?		Yes		No

Page	3	Ωf	3

OCH/LPH-810 (12/04)	
NAME	

21. Security provided for the pharmacy area - Explain alarm system:					
22. Are controls in effect in the pharmacy department to prevent theft and diversion o controlled substances?	 f	Yes		No	
23. Has a controlled substances inventory been taken?		Yes		No	
Is it on site and properly documented? Date taken:		Yes		No	
24. Are all controlled substance purchase records to be kept on site?		Yes		No	
25. Will all controlled substances invoices be initialed and dated by a pharmacist?		Yes		No	
26. Are Schedule 2 invoices filed separately from all other purchase invoices?		Yes		No	
27. Are Schedules 3,4, and 5 controlled substance invoices filed separately or readily retrievable?	, 	Yes		No	
28. Will DEA-222 Schedule 2 Order Forms be maintained as required?		Yes		No	
29. How are prescription refill records maintained? Check one:					
☐ Initialed and dated on back of Rx					
□ Paper profile maintained (See Below)					
☐ Computer IF PAPER PROFILE IS TO BE MAINTAINED, PLEASE ANSWER THE FOLLOWING	⊋ ∙				
30. Does the profile system indicate the drug name, strength, and directions for use of					
drugs entered?		Yes		No	
31. Are all prescriptions entered on the system - new Rx's and refills?		Yes		No	
32. Are DAW prescriptions so designated?		Yes		No	
33. Is the manufacturer's or distributor's name indicated if drug product selection is us prescription is written generically?	sed or if □	Yes		No	
34. Is the pharmacist who filled or refilled the prescription initialing each entry?		Yes		No	
35. Are the profiles maintained for five years?		Yes		No	
FOR OUT-OF-STATE PHARMACIES ONLY					
Section 333.17763 of the Occupational Regulation Sections of the Michigan Public Health Code posell, distribute, or deliver a prescription drug when the prescription for the drug is received by mail		se of the	mail	to	
36. Do you receive prescriptions by mail and deliver those same prescriptions drugs	by mail? □	Yes		No	
CERTIFICATION					
I,, R.Ph., certify that my responses to this che	cklist are true	and ac	curate		
and that I am employed as the Pharmacist-in-Charge or the Owner of this pharmacy.					
Signature of Pharmacist-in-Charge	Date				
Signature of Owner	Date				_
	1				

The Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.